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September 28, 2021

Via CDX

TSCA Confidential Business Information Center (7407M)

WJC East - Room 6428 Attn: Section 8(e)

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004-3302

Subject: TSCA 8(e) cases with patent issues

Dear Section 8(e) CBI Substantiation Evaluation Team

is providing the supplemental substantiations for the TSCA Section 8(e) notification for which the EPA identified patent substantiation concerns. We were able to verify the patent information for 48 out of 59 identified notifications; see Table 1. During our review we identified 7 submissions had incorrect answer stating the substance was patented where the substance was not patented; see Table 2. We are also providing patent information for 5 recent submissions as requested on September 27, 2021; see Table 3. The information for the remaining 4 submissions will be provided by October 28, 2021 per granted on September 27, 2021 30-day extension; see Table 4.

Table 1.

| TSCA 8(e) Notification | Patent # |
|-------------------------------|-------------------------------------------------------------|
| 8eHQ-19-21908 | A patent for this substance is currently pending. |
| 8eHQ-19-21930 | |
| 8eHQ-19-21934 | |
| 8eHQ-19-21943 | |
| 8eHQ-19-21949 | |
| 8eHQ-20-22047 | (1., 2., 3., 5., 7., 9. & 10.) (4. & 6.) (8.) |
| 8eHQ-20-22243 | |
| 8eHQ-20-22307 | A patent for this substance is currently pending. |
| 8eHQ-20-22310 | |
| 8eHQ-20-22331 | Patents for this substance are currently pending () |

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| 8eHQ-20-22332 | A patent for this substance is currently pending (). |
| 8eHQ-20-22347 | A patent for this substance is currently pending. |
| 8eHQ-20-22351 | |
| 8eHQ-20-22355 | A patent for this substance is currently pending. |
| 8eHQ-20-22359 | A patent for this substance is currently pending. |
| 8eHQ-20-22364 | |
| 8eHQ-20-22388 | |
| 8eHQ-20-22392 | |
| 8eHQ-20-22419 | |
| 8eHQ-21-22426 | A patent for this substance is currently pending. |
| 8eHQ-21-22430 | A patent for this substance is currently pending. |
| 8eHQ-21-22440 | |
| 8eHQ-21-22445 | A patent for this substance is currently pending (). |
| 8eHQ-21-22449 | |
| 8eHQ-21-22453 | A patent for this substance is currently pending (). |
| 8eHQ-21-22457 | |
| 8eHQ-21-22459 | A patent for this substance is currently pending (). |
| 8eHQ-21-22480 | A patent for this substance is currently pending (). |
| 8eHQ-21-22486 | |
| 8eHQ-21-22492 | 1. 2. |
| 8eHQ-21-22506 | |
| 8eHQ-21-22550 | A patent for this substance is currently pending (). |
| 8eHQ-21-22574 | A patent for this substance is currently pending (). |
| 8eHQ-21-22582 | |
| 8eHQ-21-22603 | |
| 8eHQ-21-22628 | |

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|---------------|----------------------------------------------------------|
| 8eHQ-21-22632 | A patent for this substance is currently pending (). |
| 8eHQ-21-22636 | A patent for this substance is currently pending (). |
| 8eHQ-21-22645 | A patent for this substance is currently pending (). |
| 8eHQ-21-22650 | |
| 8eHQ-21-22664 | |
| 8eHQ-21-22675 | |
| 8eHQ-21-22691 | A patent for this substance is currently pending. |
| 8eHQ-21-22698 | |
| 8eHQ-21-22705 | |
| 8eHQ-21-22714 | A patent for this substance is currently pending (). |
| 8eHQ-21-22720 | |
| 8eHQ-21-22729 | A patent for this substance is currently pending (). |

Table 2.

| TSCA 8(e) Notification | Patent # |
|-------------------------------|----------------------------------------------------------------|
| 8eHQ-19-21938 | To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22467 | 2. To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22600 | To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22611 | To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22693 | To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22710 | To the best of our knowledge the substance is not patented. |
| 8eHQ-21-22726 | To the best of our knowledge the substance is not patented. |

Table 3.

| TSCA 8(e) Notification | Patent # |
|-------------------------------|-------------------------------------------------------------|
| 8EHQ-21-22737 | To the best of our knowledge the substance is not patented. |

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|---------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 8EHQ-21-22763 | |
| 8EHQ-21-22774 | A patent for this substance is currently pending (). |
| 8EHQ-21-22780 | 1. 2. To the best of our knowledge the substance is not patented. 3. To the best of our knowledge the substance is not patented. 4. |
| 8EHQ-21-22794 | A patent for this substance is currently pending. |

Table 4.

| TSCA 8(e) Notification | Patent # |
|-------------------------------|--------------------------------------------------|
| 8eHQ-20-22156 | Information will be provided by October 28, 2021 |
| 8eHQ-21-22557 | Information will be provided by October 28, 2021 |
| 8eHQ-21-22594 | Information will be provided by October 28, 2021 |
| 8eHQ-21-22641 | Information will be provided by October 28, 2021 |

is supplying the substantiation via TSCA Communication module in CDX as agreed upon during our discussions. The supplemental substantiation is provided below.

The corporation asserts and substantiates this CBI information with the understanding that the Agency will maintain this information as confidential. If the Agency denies in part or in total this CBI claim, then it is our understanding that the EPA will notify the corporation with respect to the reasons for denial in accordance with §14(g)(1)(B).

Q. Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

A1. Supplemental substantiation for the TSCA 8(e) submission where the substance(s) is patented, or patent is pending.

Patents contain many embodiments of an invention, with no obligation to identify commercial embodiments. A patent holder must disclose their best mode but has no obligation to identify which embodiment is the best mode of the invention or if that embodiment is the commercial embodiment. Further, even though a commercial product may be covered by a patent, it is entirely possible that the patent does not disclose all aspects of the covered commercial product and/or that the commercial embodiment itself is not identified as such within the patent.

While the compound has been included in a patent, there are typically other compounds also identified in the patent and countless potential possible commercial embodiments (e.g., countless potential formulations in a compound patent). In this instance, the specifics of our commercial embodiment(s) are confidential business information and/or trade secrets.

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A2. Supplemental substantiation for the TSCA 8(e) submission where the substance(s) is not patented.

To the best of our knowledge the substance is not patented.

Very often the chemicals that we have submitted have not been patented yet or in some cases will be held as trade secret or a final decision may not have been made at the time of submission. Regardless, even if a patent is eventually filed, it will generally describe a series of a class of compounds for a given use and there will be far fewer substances in the examples of patents. Additionally, while a patent may describe the favored compound in one of the examples, it will typically never point to that compound or link it to a tradename. There are other times that it might be advantageous not to file a patent at all and maintain a new compound as a trade secret.

Please note that a sanitized version of this letter is enclosed, treating the company identity as Confidential Business Information. The information considered confidential has been redacted in accordance with U.S. EPA's policy.

Please direct all correspondence to the technical contact below.

Sincerely,

Technical Contact: